Australian Government

Department of Health

Ministerial Discretion Guidelines

December 2019

Disclaimer

These Guidelines are designed as a general guide for pharmacists making a request for approval by the Minister for Health under section 90A of the *National Health Act 1953* (the Act). It should not be used as a basis for legal interpretation or as a definitive reference.

For more precise and detailed information please consult the relevant sections in the Act and the Explanatory Memorandum.

The Minister and the Commonwealth Government accept no responsibility arising from use of, or reliance on, this document.

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DEFINITIONS

In these Guidelines:

- "the Act" means the *National Health Act 1953*;
- "AAT" means the Administrative Appeals Tribunal;
- "Authority" means the Australian Community Pharmacy Authority established under section 99J of the *National Health Act 1953* to perform functions under section 99K of the Act;
- "Department" means the Department of Health;
- "Discretionary power" means the discretionary power provided to the Minister for Health under subsection 90A(2) of the Act;
- "Minister" means the Minister for Health;
- "pharmaceutical benefits" means drugs or medicinal preparations for which benefits will be paid by the Commonwealth, in accordance with Part VII of the Act;
- "the Pharmacy Location Rules" means the rules determined by the Minister under section 99L of the Act;
- "Request" means a request to the Minister under section 90B of the Act that the Minister exercise the power under subsection 90A(2) of the Act;
- "Secretary" means the Secretary of the Department of Health;
- "Secretary's delegate" means the person/s in the Department of Health to whom the Secretary's functions under section 90 of the Act have been delegated;
- "application" means an application made under section 90 of the Act for approval to supply pharmaceutical benefits at particular premises which is referred to the Authority to determine whether the requirements of the Pharmacy Location Rules have been met.

1 INTRODUCTION

1.1 The Guidelines

The purpose of these Guidelines is to assist a pharmacist who is considering making a request to the Minister for Health, for approval to supply pharmaceutical benefits at particular pharmacy premises.

A summary of the legislative provisions relevant to the Minister's discretionary power is at Appendix 1.

A flowchart showing the decision-making process is at Appendix 2.

1.2 The Pharmacy Location Rules

The Act provides that the Secretary of the Department of Health may approve a pharmacist to supply pharmaceutical benefits at particular premises. The Secretary may only approve a pharmacist if:

a) the Australian Community Pharmacy Authority (the Authority) has recommended the application be approved; and

b) the pharmacist is permitted under the relevant State or Territory law in which the premises are situated, to carry on a pharmacy business.

In making its recommendations to the Secretary, the Authority must comply with the rules determined by the Minister for Health (the Pharmacy Location Rules).

The Secretary has delegated the power to approve a pharmacist at particular premises to certain officers in the Department of Health.

1.3 The Minister's discretionary power

The Minister's discretionary power only arises in situations where a pharmacist has not been approved by the Secretary's delegate to supply pharmaceutical benefits at particular premises, because the requirements of the Pharmacy Location Rules were not met.

The discretionary power enables the Minister to approve a pharmacist to supply pharmaceutical benefits at particular premises in circumstances where the Minister is satisfied that:

a) the decision of the Secretary will result in a community[1] being left without reasonable access[2] to pharmaceutical benefits supplied by an approved pharmacist; and

b) it is in the public interest to approve the pharmacist.

The intention of the discretionary power is to enable the Minister to respond on an individual and timely basis in circumstances where the application of the Pharmacy Location Rules has

[1] *community* means a group of people that, in the opinion of the Minister, constitutes a community; and

[2] *reasonable access*, in relation to the supply of pharmaceutical benefits supplied by an approved pharmacist, means access that, in the opinion of the Minister is reasonable.

resulted in a community being left without reasonable access to the supply of Pharmaceutical Benefits Scheme (PBS) medicines and it is in the public interest to grant approval.

When determining whether these two criteria are met, the Minister will have regard to the individual circumstances of each case. The circumstances in which the commercial interests of the pharmacist making the request, or of any other party, are relevant to these criteria are likely to be limited. The purpose of the legislative scheme is 'not concerned with minimising competition in the pharmaceutical industry but with reducing the Commonwealth's financial burden in providing pharmaceutical benefits while maintaining an acceptable level of community service'.[3]

The Minister's discretionary power cannot be delegated to another person. Any decision regarding the exercise of the discretionary power must be made by the Minister personally.

The Department has responsibility for managing all aspects of requests made to the Minister.

2 MAKING A REQUEST

2.1 When a request can be made to the Minister

The Minister can only consider a request if the Secretary's delegate has made a decision not to approve the pharmacist because the application failed to meet the requirements of the Pharmacy Location Rules.

If the pharmacist has initiated proceedings before the AAT or a federal court in respect of a decision by the Secretary's delegate not to approve the application, those proceedings must be finalised (i.e. discontinued, withdrawn or dismissed) before a request to the Minister can be made. If such a proceeding is initiated after a request is made, then the request will be taken to have been withdrawn.

2.2 Making a request on the approved form

A request must be made on the approved form and sent to the PBS Approved Suppliers Portal PBSApprovedSuppliers. The request form can be downloaded from the Department of Health website or mailed to you by phoning 1800 316 389.

2.3 Making a request on behalf of a pharmacist

If the pharmacist/s making the request is being represented by another person/company (e.g. pharmacy broker), then a signed and dated letter of authority by the pharmacist, appointing the other person/company to act on behalf of the pharmacist/s in respect of the request, must be provided.

2.4 Contact details

Email:	90Apharmacy@health.gov.au
Telephone:	1800 316 389

[3] *Kong v Minister for Health* (2014) 227 FCR 215, [97], [179], [183]; *Pharmacy Restructuring Authority v Martin* (1994) 53 FCR 589, 597.

2.5 Timing

A request must be made within 30 calendar days after the day:

a) the pharmacist is notified of the decision by the Secretary's delegate not to approve the pharmacist to supply pharmaceutical benefits; or

b) the proceeding in the AAT or a federal court is discontinued, withdrawn or dismissed, if the decision by the Secretary's delegate not to approve the pharmacist was/is the subject of a proceeding in the AAT or a federal court; or

c) the pharmacist is given a copy of the AAT's decision or a federal court makes an order, which affirms the decision of the Secretary's delegate/ AAT not to approve the pharmacist to supply pharmaceutical benefits.

When calculating the 30 day time period, the day specified in paragraphs (a) to (c) above will not be included (eg, if a pharmacist is notified of the decision of the Secretary's delegate on 2 August, the 30 day time period begins on 3 August)[4]. If the 30 day time period ends on a Saturday, Sunday or a public holiday in the Australian Capital Territory (ACT), then the request may be made on the next day that is not a Saturday, Sunday or a public holiday in the ACT[5].

A request will be treated as 'made' when it is received by the Department in Canberra via the PBS Approved Suppliers Portal PBSApprovedSuppliers or its designated email address (90Apharmacy@health.gov.au). The time when the request is received will be determined according to Australian Eastern Standard Time.

2.6 Mandatory requirements

The following attachments must be included with the request:

a) a copy of:

   i) the letter from the Secretary's delegate, notifying the pharmacist of the decision not to approve the pharmacist to supply pharmaceutical benefits; or

   ii) the order or decision of the AAT/ a federal court affirming the decision of the Secretary's delegate; or

   iii) notice that the proceeding in the AAT/ a federal court is discontinued, withdrawn or dismissed; and

b) evidence to address the following if, in considering the application, the Authority was not satisfied that one or more of these requirement(s) in the Pharmacy Location Rules was met:

   iv) legal right to occupy the proposed premises;

   v) the proposed premises could be used for the operation of a pharmacy under applicable local government and State and Territory laws relating to land development;

[4] *Interpretation Act 1901* s 36(1)(6))

[5] *Acts Interpretation Act 1901* s 36(2) and (3)(a)

vi) the proposed premises would be accessible by members of the public (and not restricted to certain members of the public, such as patients of a particular medical centre); and

c) a brief summary of the request, including:

i) the reason/s the Authority did not recommend the application be approved (refer to the letter from the Authority's secretariat advising the reasons why the application did not satisfy the requirement/s of the Pharmacy Location Rules); and

ii) the applicant's submissions about why the decision of the Secretary's delegate, not to approve the pharmacist to supply pharmaceutical benefits at the proposed premises, will result in a community being left without reasonable access to the supply of pharmaceutical benefits by an approved pharmacist; and

iii) the applicant's submissions about why it is in the public interest for the Minister to approve the pharmacist to supply pharmaceutical benefits at the proposed premises; and

d) a discussion about the community and surrounding area. The discussion should include the following:

i) a description of the area/community in which the proposed pharmacy premises is located; and

ii) details about the distance between the proposed pharmacy and other approved pharmacies in the surrounding area; and

iii) information about access to the supply of pharmaceutical benefits at other pharmacies and reasons why that may not be considered reasonable; and

iv) any relevant geographical or other features in the area surrounding the proposed pharmacy premises that would affect a particular community's access to the supply of pharmaceutical benefits at other approved pharmacies (for example, an unbroken railway line or a large body of water); and

v) any demographics that may be relevant, including particular subsets of the community for whom local pharmacy access may differ from that of the general population (ensure that the source of any information, such as population data, is properly cited).

3 PROCESSING REQUESTS

3.1 Assessing validity of a request

Upon receipt of a request, the Department will assess the request to determine whether it is valid, specifically if the request:

a) is one for which the discretionary power is available (paragraph 2.1 refers);

b) has been made on the approved form (paragraph 2.2 refers); and

c) has been made within the required timeframe (paragraph 2.5 refers).

Each request will be issued with an identification number. This identification number will allow the pharmacist making the request, the Department and the Minister to monitor the progress of the request.

The Department will advise the pharmacist making the request, in writing within ten (10) working days of receipt of the request, if the request is valid or invalid.

If the request is valid, the Department will prepare a submission for the Minister's consideration, which will include the request, a summary of the request, and any further information received from the applicant or a third party in response to a notice from the Minister (paragraphs 3.2 and 4.4 refer).

If the request is invalid, the Department will return the request to the pharmacist, including the reasons why the request is invalid.

3.2 Consulting third parties

The Minister (or the Department on behalf of the Minister) may, at any time during the process, seek information from any other party.

The Department will normally allow fourteen (14) days for any other party to provide comments or information relevant to the request.

Any comments provided should be limited to addressing the 2 criteria referred to in paragraph 1.3 above, or any specific information requested in the notice.

If the information requested of any other party is not provided within the specified timeframe, the Minister is not required to take any further action to obtain the information. The Minister is not required to (but may) consider any further information provided if it is received outside of the specified timeframe.

Any third party that provided comment on a request will be advised of the Minister's decision.

4 STAGE 1 – DECIDING WHETHER TO CONSIDER A REQUEST

4.1 Timeframe to decide whether to consider a request

The Minister has three months from the date a valid request is received, in which to decide whether or not to consider the request (stage 1 in the process).

The Minister is not under any legal obligation to consider a request and cannot be compelled to do so. If the Minister does not make a decision within the three month period, he or she will be taken to have decided not to consider the request.

4.2 Departmental submission (stage 1) to the Minister

The Department will provide the Minister with a submission, which will include the request, a summary of the request, research by the Department and any further information received from the applicant or a third party in response to a notice issued by the Minister (paragraphs 3.2 and 4.4 refer).

4.3 If the Minister decides not to consider a request

If the Minister decides not to consider a request, the Department will advise the pharmacist making the request as soon as practicable after the decision (not to consider the request) was made. This includes circumstances where no decision has been made and the Minister is taken to have decided not to consider the request (paragraph 4.1 refers).

The effect of the Minister's decision to not consider the request is that the decision of the Secretary's delegate not to approve the pharmacist stands. The pharmacist may then consider seeking a review of the decision of the Secretary's delegate by the AAT or Federal Court, if they have not already done so.

4.4 If the Minister decides to consider a request

If the Minister decides to consider a request (stage 1), the Department will advise the pharmacist making the request as soon as practicable after that decision has been made.

The Minister (or the Department acting on behalf of the Minister) may also decide to seek additional information from the pharmacist making the request, or any other third party.

If the information requested of the pharmacist making the request is not provided within the specified timeframe, the Minister may treat the request as having been withdrawn.

5 STAGE 2 – DECIDING WHETHER TO APPROVE A REQUEST

5.1 Timeframe to decide whether to approve a request

The Minister has three months, after deciding to consider a request, in which to decide whether or not to exercise the discretionary power to approve the request (stage 2 in the process).

The Minister is not under any legal obligation to exercise the discretionary power to approve a pharmacist to supply pharmaceutical benefits at particular premises, and cannot be compelled to do so. If the Minister does not make a decision within the three month period, the Minister is taken to have decided not to exercise the discretionary power.

5.2 Departmental submission (stage 2) to the Minister

The Department will provide the Minister with a submission, which will include the request, a summary of the request, research by the Department and any further information received from the applicant or a third party in response to a notice issued by the Minister (paragraphs 3.2 and 4.4 refer).

5.3 If the Minister decides not to approve a request

If the Minister decides not to approve a request, the Department will advise the pharmacist making the request, as well as any other party who provided comment on the request, in writing, of the Minister's decision. This includes circumstances where no decision has been made and the Minister is taken to have decided not to approve the request (paragraph 5.1 refers).

The effect of the Minister's decision to not approve a request is that the decision of the Secretary's delegate not to approve the pharmacist stands. The pharmacist may then consider seeking a review of the decision of the Secretary's delegate by the AAT or Federal Court, if they have not already done so.

5.4 If the Minister decides to approve a request

If the Minister decides to exercise the discretionary power, the Minister's decision substitutes the decision of the Secretary's delegate not to approve the pharmacist, with a decision to approve the pharmacist to supply pharmaceutical benefits at the proposed premises.

As soon as practicable, the Department will notify the pharmacist and the Secretary's delegate of the Minister's decision. The Secretary's delegate will allocate an approval number to the pharmacist.

After the Department has advised the pharmacist making the request and the Secretary's delegate, the Department will also write to any other party who responded to an invitation to comment on the request by the Department or the Minister.

Appendix 1

LEGISLATION

The Act sets out the legislative basis for the Minister's discretionary power.
Sections 90A - 90E set out the:

i. power to approve a pharmacist to supply Pharmaceutical Benefits Scheme (PBS) medicines at particular premises (section 90A);

ii. circumstances in which the discretionary power is/is not available (section 90A);

iii. conditions that must be satisfied in order for the discretionary power to be exercised (section 90A);

iv. non-compellable nature of the discretionary power (section 90A(5));

v. the form in which a request must be made (subsection 90B(2));

vi. timeframe in which requests must be made (subsection 90B(3));

vii. timeframe in which the Minister will make a decision about whether to consider a request (subsection 90B(4) and 90B(5));

viii. procedures for advising pharmacists of decisions made by the Minister (subsection 90B(6));

ix. arrangements for dealing with requests where the applicant has sought a review of the decision of the Secretary's delegate (section 90C);

x. arrangements for seeking further information from an applicant (or any other person) to assist in making a decision about a request (section 90D); and

xi. conditions of approval and rights and obligations of approved pharmacists (section 90E).

Appendix 2

MINISTER'S DISCRETIONARY POWER FLOWCHART